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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/779,852 | 02/18/2004 | Shinji Yamamori | Q79958 | 9460 |

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| EXAMINER |
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TOTH, KAREN E

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| ART UNIT | PAPER NUMBER |
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3735

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/779,852 | Applicant(s) YAMAMORI ET AL. | |
| | Examiner Karen E. Toth | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-12 and 17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9 and 17 is/are rejected.
- 7) ☒ Claim(s) 1,4-5 and 10-12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/27/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Claims 6-8, 13-16, and 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 May 2006.
2. Applicant's election without traverse of Invention I, claims 1-5, 9-12, and 17 in the reply filed on 18 May 2006 is acknowledged.

Claim Objections

3. Claims 1, 4, and 5 are objected to as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, it is not clear whether the combination/subcombination in claim 1 is intended to claim the carbon dioxide sensor; since the claim positively refers to the "light emitter of the sensor" it will be treated as claiming the sensor.

Regarding claim 4, it is not clear what is meant by "an extending direction of the shaft member." It is suggested that the claim be amended to clearly define the desired direction of extension and therefore clearly claim the desired structure.

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Regarding claim 5, it is not clear what is meant by "a face of the living body." It is suggested that this be changed to --the plane represented by the face of the living body--.

4. Claim 3 is objected to because of the following informalities: Claim 3 states "than a size of the hole." For clarity, it is suggested that this be changed to --than the size of the hole--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

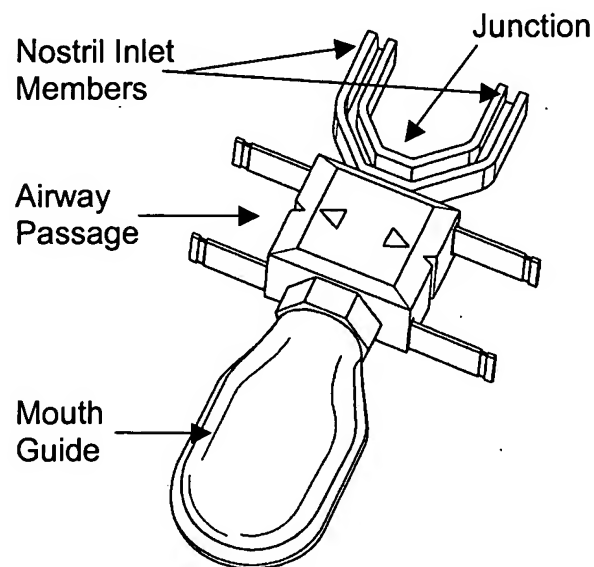
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Star'836 (US Patent Application Publication 2005/0245836) in view of Phillips'637 (US Patent 6726637).

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Regarding Claim 1, Star'836 discloses a device comprising a carbon dioxide sensor (element 12); an airway case that is adapted to be disposed below nostrils of a body and has an airway passage that crosses the light beam of the sensor; and a mouth guide that is adapted to be disposed in front of the mouth of the body and create a space that

communicates with the airway passage (see Figure 1 of this action, taken from Star's Figure 14). Star'836 does not disclose the mouth guide being pivotally supported on the airway case.

Figure 1

Phillips'637 teaches an exhaled carbon dioxide device comprising a mouth guide (element 20) that is pivotally connected (column 3, lines 53-55) to an airway passage (element 50), in order to increase the comfort of the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Star'836 with the pivotable connection of the mouth guide to the airway case, as taught by Phillips'637, in order to increase the comfort of the patient.

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7. Claims 2, 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Star'836 in view of Phillips'637, as applied to claim 1 above, and further in view of Cannon'816 (US Patent Application Publication 2004/0003816).

Regarding claim 2, Star'836 in view of Phillips'637 discloses all the elements of the current invention, except for the mouth guide comprising a shaft member which is fitted into a hole in the airway case so that the mouth guide may pivot about the hole.

Cannon'816 discloses a device comprising a mouth guide (element 12) and a shaft (element 24), wherein the shaft of the mouth guide is inserted into a hole in order to allow the mouth guide to pivot (Figure 1; paragraph [0023]), in order to increase the patient's comfort, since pivoting around a shaft is well known in the art. The examiner notes that the shaft of Cannon'816 is not integrally molded as part of the mouth guide; however, the final product has the same structure, regardless of the method of formation, and therefore is not patentably distinguishable (see MPEP §2113).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Star'836 in view of Phillips'637, and comprised the pivoting mechanism with a shaft inserted into a hole about which it

Regarding claim 4, Star'836 in view of Phillips'637 and Cannon'816 discloses all the elements of the current invention, as applied to Claim 2, except for either the airway case or mouth guide being formed of an elastic material allowing stretching away from the shaft member.

Phillips'637 further teaches that the apparatus may be formed of a material such as plastic (column 4, lines 9-10), which may be flexible and therefore allow stretching,

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so that the positioning of the apparatus may be changed as needed to efficiently capture the patient's exhaled breath.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Star'836 in view of Phillips'637 and Cannon'816, and formed the airway case or mouth guide of an elastic material, as taught by Phillips'637, in order to allow the position of the apparatus to be changed as needed to efficiently capture the patient's exhaled breath.

Regarding claim 5, Star'836 in view of Phillips'637 and Cannon'816 discloses all the elements of the current invention, as applied to Claim 2, except for the shaft member being disposed parallel to the patient's face, and permitting rotation about the shaft, perpendicular to the patient's face.

Cannon'816 further discloses that the shaft member is disposed in a direction parallel to the patient's face (Figure 1), thereby permitting rotation about it in a direction perpendicular to the patient's face (Figure 1), in order to increase the patient's comfort while wearing the apparatus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Star'836 in view of Phillips'637 and Cannon'816 with the shaft member being disposed in a direction parallel to the patient's face and permitting rotation about the shaft in a direction perpendicular to the patient's face, in order to increase the patient's comfort while wearing the apparatus.

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8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Star'836 in view of Phillips'637 and Cannon'816, as applied to claim 2 above, and further in view of Yang'218 (US Patent 6739218).

Star'836 in view of Phillips'637 and Cannon'816 discloses all the elements of the current invention except for the shaft member being formed of a flexible material and having a size no less than the size of the hole.

Cannon'816 further teaches forming the shaft member no smaller than the size of the hole (figures 1, 2, 5, 6), so the hinge moves securely.

Yang'218 teaches a device comprising a shaft member that fits into a hole to allow the device to pivot. Said shaft member (element 56) is formed of a flexible material (column 4, line 73), in order to increase the resilience of the component.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Star'836 in view of Phillips'637 and Cannon'816 with a flexible shaft, as taught by Yang'218, that is sized no smaller than its hole, as taught by Cannon'816, so that the components are resilient and the hinge moves securely.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Star'836 in view of Phillips'637 as applied to claim 1 above, and further in view of Starr'049 (US Patent 6849049).

Regarding Claim 9, Star'836 in view of Phillips'637 discloses all the elements of the current invention as applied to Claim 1 above. Star'836 further discloses that the

airway adapter comprises an inlet member adapted to be inserted into a nostril having a passage for guiding nasal expiration into the airway passage (see Figure 1 above).

Star'836 in view of Phillips'637 does not disclose a vent hole.

Starr'049 teaches a patient monitoring and sensing device comprising an inlet member (element 202) adapted to be inserted into a nostril having a passage for guiding nasal expiration into an airway passage (element 214) and a vent hole (element 212), so that excess expiration does not overwhelm the sensing system.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Star'836 in view of Phillips'637 with a vent hole, as taught by Starr'049, so that excess expiration does not overwhelm the sensing system.

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Star'836 in view of Phillips'637, and further in view of Yamamori'746 (US Patent Application Publication 2002/0122746).

Star'836 discloses a device comprising carbon dioxide sensor (element 12); an airway case that is adapted to be disposed below nostrils of a body and has an airway passage that crosses the light beam of the sensor; and a mouth guide that is adapted to be disposed in front of the mouth of the body and create a space that communicates with the airway passage (see Figure 1 above). Star'836 does not disclose the sensor comprising a light emitter and a light receiver, or the mouth guide being pivotably supported on the airway case.

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Phillips'637 teaches an exhaled carbon dioxide device comprising a mouth guide (element 20) that is pivotally connected (column 3, lines 53-55) to an airway passage (element 50), in order to increase the comfort of the patient.

Yamamori'746 teaches a carbon dioxide sensor for use in measuring exhaled breath comprising a light emitter (element 2) and a light receiver (element 3), so that carbon dioxide molecules may be efficiently measured.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Star'836, with the pivotable connection of the mouth guide to the airway case, as taught by Phillips'637, in order to increase the comfort of the patient, and included a light emitter and light receiver in the carbon dioxide sensor, as taught by Yamamori'746, so that carbon dioxide molecules may be efficiently measured.

Allowable Subject Matter

11. Claims 10-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the structure of Claims 10-12, including, *inter-alia*, forming a vent hole at the junction between two tube inlet members that are adapted to be inserted into nostrils.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6817359 to Deas, which discloses a pivotable airway adapter.

US Patent 5046491 to Derrick, which discloses an apparatus for collecting and analyzing exhaled breath.

US Patent Application Publication 2001/0031929 to O'Toole, which discloses an apparatus for collecting and analyzing exhaled breath.

US Patent 2370016 to Deitch, which discloses a device with a mouth guide and a pivoting shaft.

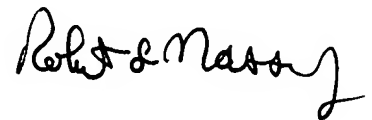
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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